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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/553,406	05/05/97	BARNIKOL	DT-2179

HM11/1210

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EXAMINER

GUPTA, A

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 12/10/98

Please find below and/or attached an Office communication concerning this application or proceeding.

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EXAMINER

ART UNIT

PAPER NUMBER

22

Below is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

DATE MAILED:

ADVISORY ACTION

■ THE PERIOD FOR RESPONSE

- a) ■ is extended to run ____ or continues to run 3 Months from the date of the final rejection.
- b) ☐ expires three months from the date of the final rejection or as to the mailing date of this Advisory Action, whichever is later. In no event however, will the statutory period for response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response as set forth in b) above.

- Appellant's Brief is due in accordance with 37 CFR 1.192(a).
- Applicant's response to the final rejection, filed ____, has been considered with the following effect, but is not deemed to place the case in condition for allowance.

1. ☐ The proposed amendments to the claim/and or specification will not be entered and the final rejection stands because:
- a. ☐ There is no convincing showing under 37 CFR 1.116(b) why the proposed amendment is necessary and was not earlier presented.
- b. ☐ They raise new issues that would require further consideration and/or search. (See note).
- c. ☐ They raise the issue of new matter (See note).
- d. ☐ They are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.
- e. ☐ They present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: ____.

2. ☐ Newly proposed or amended claims ____ would be allowed if submitted in a separately filed amendment canceling the non-allowable claims.
3. ■ Upon the filing of an appeal, the proposed amendment ■ will be entered ☐ will not be entered and the status of the claims will be as follows:

Claims allowed: NONE

Claims objected to: NONE

Claims rejected: 6-10

However;

■ Applicant's response has overcome the following rejection(s): Applicants argue that the difference between the claimed invention and the reference is that in the instant application, there is a separation of cross-linked hemoglobin molecules into different molecular weight fractions, whereas in the reference, there is no separation of cross-linked hemoglobin into different factions, but only an analysis as regards the fact that the molecular size distribution of the molecules obtained by the cross-linked reactions is broad. Applicants also state that the reference does not describe the separation of molecular weights. Applicant's arguments have been considered but not found persuasive. It is well known that Gel permeation chromatography is used to separate molecules of different sizes and is dependant on the partition between solvent and a stationary phase of defined porosity. The reference teaches the gel permeation of the hyperpolymer hemoglobin, from a crude solution containing both freshly cross linked and uncross linked hemoglobin (see examples). Therefore, the gel chromatographic step would separate the hemoglobin based on molecular size. Applicants have argued that there is no separation of cross-linked hemoglobin into different factions. However, it should be noted that the reference utilizes the same starting material as disclosed in the specification, the starting material is cross linked with the same cross-link agent as disclosed in the specification, and the same Gel chromatographic gel, Sephacryl S-400, is used for separation. Therefore, separation of cross-linked hemoglobin into different factions would necessarily have to be achieved.

For the Bonhard reference, applicants argue that it would not be obvious to use the teaching of the reference since the compounds of the instant application and the reference have "completely different properties" in their physical and chemical behavior. However, the starting material of the applicants is similar to applicants, i.e. human hemoglobin, and the end product is cross linked with glutar-

aldehyde (see example 5 in the reference). Therefore, the compounds of the reference are not dissimilar to those claimed and thus one would expect separation of un-cross linked hemoglobin from cross-linked hemoglobin for hyperpolymeric hemoglobin as well. It is unclear as to what applicants mean when they state "there is no noncross-linked hemoglobin in the starting material". However, examples of the instant application utilize human hemoglobin as the starting material. This hemoglobin is not cross-linked and therefore the starting material would only contain noncross-linked hemoglobin. Applicants are requested to clarify what starting material they are making reference to.

All rejection maintained for the reasons set forth in the previous office actions and the reasons set forth above.

4. ☐ The affidavit, exhibit or request for reconsideration has been considered, but does not overcome the rejection because ____.
5. ☐ The affidavit or exhibit will not be considered because applicant has not shown good and sufficient reasons why it was not earlier presented.
- ☐ The proposed drawing correction ☐ has ☐ has not been approved by the examiner.
- ☐ Other



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